



MEMORANDUM

To: Members of the House Judiciary Committee

From: Wendy Block, Director of Health Policy and Human Resources

Subject: Chamber Opposes Repeal of FDA Defense Legislation, HBs 4316-18

Date: March 18, 2009

The purpose of this memorandum is to urge you to **oppose House Bills 4316-18**, legislation to retroactively repeal one of Michigan's key legal reform laws, the FDA Defense law, and create a cause of action against drug manufacturers under the Michigan Consumer Protection Act.

There is a lot of misrepresentation about Michigan's existing FDA Defense law. Therefore, we think it's time to set the record straight and highlight the importance of retaining current law.

FACT: Drug companies do not have blanket immunity under Michigan's FDA defense law. A Michigan resident may proceed with a lawsuit against a drug manufacturer if they first follow an established administrative process – referred to as a “citizen petition” -- that results in a finding by the FDA of wrongdoing by the drug manufacturer. The current law and process strike an appropriate balance, permitting the FDA to do its job, but allowing punishment for companies that withhold valuable information and interfere with the drug approval process.

FACT: Michigan is not the only state that has this type of law. Like Michigan, several states limit liability in suits alleging harm from FDA-approved prescription drugs. Statutes in New Jersey, North Carolina and Texas also create presumptions of adequacy based on FDA approval. In addition, it is important to note that legislation was introduced in both Georgia and Oklahoma this session that is modeled after Michigan's law.

FACT: The biopharmaceutical industry currently contributes \$10 billion to the state's economy each year and employs close to 99,000 jobs at an average wage of over \$73,000. This industry is vital to Michigan's economy; repeal of Michigan's FDA Defense law will send a message to the life science industry that Michigan is closed for business.

FACT: The Supreme Court's recent decision (*Wyeth v. Levine*) has made Michigan's FDA Defense law even more necessary as it invites states to determine the extent to which lawsuits challenging FDA decisions should be allowed. Michigan made this determination when it enacted the FDA Defense and removing that defense would lead to increased litigation, unclear drug labeling guidelines and limitations on access to drug treatments.

FACT: In states where lawsuits have been filed against drug manufacturers, juries have ruled in many cases that the litigation was frivolous and/or that the science did not support the plaintiffs' claims that the pharmaceutical drugs in question caused the injuries.

FACT: The FDA must balance the needs and hopes of patients waiting for new treatments against the need to ensure that the medicines being studied are safe and effective. Repealing Michigan's FDA defense law would imply that a drug researcher must know every possible risk before a drug can be available for patients. That is simply not possible and doing so could keep many lifesaving and life-improving medicines from ever being marketed because drug companies would fear being sued.

FACT: Health groups, individuals, biotech and business organizations support retaining the current law. They know that repealing this law is an open invitation for the trial lawyers to open their "motel" clinics and recruit litigants, whether patients have been harmed or not. This can hurt all businesses and the overall economic growth of the state. Personal injury attorneys have done this with asbestos cases and they'll surely do it with pharmaceuticals and other industries too.

Over thirteen years ago Michigan passed the FDA Defense law, a comprehensive reform law that set the pace for the rest of the country in limiting frivolous lawsuits and restoring some sanity to court verdicts. Michigan's reasonable liability reforms give our state a clear competitive advantage in the battle for jobs and investments. Repeal and/or weakening of these strong laws would be a giant step backward for the State of Michigan. We cannot afford to throw that advantage away or to swamp the state in meritless lawsuits, destroying Michigan's shot at becoming a first rate state for the life sciences industry or raising health insurance costs for Michigan employers.

We respectfully request that you and your colleagues fight to preserve and protect Michigan laws that prevent costly and endless litigation. Please support Michigan job providers by opposing HBs 4316-18. Please do not hesitate to contact me or Jim Holcomb if you have any questions at (517)371-2100.